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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|------------------|
| 10/590,204 | 05/04/2007 | Simon Bates | 09013.0010 | 5565 |
| 22852 | 7590 | 02/05/2009 | | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | EXAMINER KILPATRICK, BRYAN T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1797 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 02/05/2009 PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/590,204

Applicant(s)

BATES ET AL.

Examiner

BRYAN T. KILPATRICK

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-14 is/are pending in the application.
4a) Of the above claim(s) 2 and 3 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 4-14 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 22 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 07/30/2008
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed 27 October 2008 has been entered and fully considered.
2. Claims 1 and 4-14 are pending, claims 2 and 3 have been cancelled.

Claim Objections

Claim 6 is objected to because of the following informalities: the word "cocrtystal" appears to be a misspelling of "cocrystal." Appropriate correction is required.

Claim 10 is objected to because of the following informalities: the word "power" appears to be a misspelling of "powder." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "A method as claimed in claim 3," in the first line. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

Claims 1, 4-10, 12, and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, and 5 of U.S. Patent No. 7,372,941 (IVANISEVIC et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1, 4-10, and 14 recite a method comprised of comparing a PDF trace of a first sample of a substance with a PDF trace of a second sample of the substance to identify any similar or different solid forms, and instant claim 12 recites a method comprised of providing and grouping a plurality PDF traces of substances by similarity into groups through hierarchical cluster analysis. The claims of the prior art recite a method of comparing received diffraction patterns for similarities and then performing hierarchical cluster analysis for results. In light of paragraph [002] of the instant Specification (PDF traces are derived from X-ray powder diffraction patterns), it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed method of the prior art since it expressly recites a method in the claims that uses diffraction patterns and hierarchical cluster analysis.

Claim 11 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, and 5 of U.S. Patent No. 7,372,941 (IVANISEVIC et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 11 recites a method comprised of comparing a PDF trace of a plurality of samples of a substance with one or more PDF traces of known solid forms of the substance for identifying any

substances in the sample that have a new solid form. The claims of the prior art recite a method of comparing received diffraction patterns for similarities. In light of paragraph [002] of the instant Specification (PDF traces are derived from X-ray powder diffraction patterns), it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed method of the prior art since it expressly recites a method in the claims that uses diffraction patterns for analysis; in addition, simple substitution of one known element for another to obtain predictable results (such as comparing two different diffraction patterns for analysis, whether one of the patterns is known or unknown) is an exemplary rational of obviousness. *KSR*, 550 U.S. at_, 82 USPQ2d at 1396.

Claim 13 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, and 5 of U.S. Patent No. 7,372,941 (IVANISEVIC et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 13 recites a system comprised of a means of comparing a PDF trace of a first sample of a substance with a PDF trace of a second sample of the substance to identify any similar or different solid forms. The claims of the prior art recite a method of comparing received diffraction patterns for similarities and then performing hierarchical cluster analysis for results. In light of paragraph [002] of the instant Specification (PDF traces are derived from X-ray powder diffraction patterns), it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed method (Examiner takes the position that the method constitutes as a means of doing an action or function) of the

prior art since it expressly recites a method in the claims that uses diffraction patterns for comparative analysis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 4-14 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2003/0123057 (LEMMO et al.).

Instant claims 1, 4-10, and 14 recite a method comprised of comparing a PDF trace of a first sample of a substance with a PDF trace of a second sample of the substance to identify any similar or different solid forms. LEMMO et al. discloses a method of screening an array of samples and determining if any share spectral features, which is similar to comparing diffraction patterns, in paragraphs [0017] and [0021]-[0022], as well as the use of X-ray diffraction analysis in paragraph [0141].

Instant claim 11 recites a method comprised of comparing a PDF trace of a plurality of samples of a substance with one or more PDF traces of known solid forms of the substance for identifying any substances in the sample that have a new solid form.

LEMMO et al. discloses in paragraph [0018] the screening of an array of samples for the presence of a particular form of a compound-of-interest. In addition, paragraph [0203] presents an example of the analysis done using a known sample.

Instant claim 12 recites a method comprised of providing and grouping a plurality PDF traces of substances by similarity into groups through hierarchical cluster analysis. Paragraph [0021] and [0023] of LEMMO et al. discloses a method of analyzing and calculating similarities of a plurality of samples via clustering.

Instant claim 13 recites a system comprised of a means of comparing a PDF trace of a first sample of a substance with a PDF trace of a second sample of the substance to identify any similar or different solid forms. Paragraph [0020] of LEMMO et al. discloses a system for analyzing samples using a method as disclosed in paragraphs [0017] and [0021]-[0022] that encompasses analyzing a plurality of samples using spectral data to identify similarities.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,977,723 (LEMMO et al.) discloses a system for screening of solid forms in lines 39-50 of column 4.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRYAN T. KILPATRICK whose telephone number is (571)270-5553. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/
Primary Examiner, Art Unit 1797

BK
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